Bioway Chemistry Reagent Series

The Serum TG Reagent Kit

Detection of Triglyceride in Human Serum or Plasma on Chemistry Analyzers

Cat. No. R052K11 ***The Serum TG Reagent Kit***

SUMMARY OF TEST PROCEDURE

Figure 1: Procedure Diagram

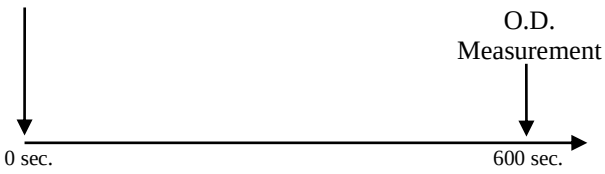

Table 1: Instrument Parameters*

Calibration method	2-point Linear	Slope of reaction	Increase
Testing wavelength	Dλ : 520 nm Sλ : 600 nm	Sample volume	3 µl
Test method	1 point end	R1 volume	300 µl
Reaction temperature	37℃		

*Refer to Figure 1 and the package insert for detail

INTENDED USE

Bioway Chemistry Reagent Series **TG Reagent Kit** (the Kit) is an assay intended for *in vitro* quantitative detection of Triglyceride in human serum or plasma on automated clinical chemistry analyzers.

SUMMARY AND EXPLANATION

Triglycerides are a kind of lipid which are absorbed from diet or produced endogenously from carbohydrates. There are many triglycerides depending on different oil source and saturated or not. They do not circulate freely in plasma but is bound to proteins and transported as macromolecular complexes called lipoproteins. Triglycerides play a very important role in the bidirectional transference of adipose and blood glucose in human bodies. Hyperlipidaemias may be a result of disbetes mellitus, nephrosis or endocrine disturbances. It also causes atherosclerosis, heart disease and stroke.

TEST PRINCIPLES

The Kit utilizes enzymatic and kinetic reactions to measure the amount of TG (mmol/L) in human serum or plasma.

$$\text{Triglycerides} + 3H_2O \xrightarrow{\text{Lipoprotein Lipase}} \text{Glycerol} + \text{Fatty acids}$$

$$\text{Glycerol} + \text{ATP} \xrightarrow{\text{GK}} \text{Glycerol-3-phosphate} + \text{ADP}$$

$$\text{Glycerol-3-phosphate} + O_2 + 3H_2O \xrightarrow{\text{GPO}} 2H_2O_2 + \text{DAP}$$

$$H_2O_2 + \text{4-APP} + \text{3,5 DHBS} \xrightarrow{\text{POD}} \text{Quinoneimine dye} + 2H_2O$$

Triglycerides are hydrolyzed by lipoprotein lipase to glycerol and free fatty acids. The glycerol is phosphorylated by adenosine triphosphate (ATP) by catalysis of glycerol kinase (GK) producing glycerol-3-phosphate and adenosine diphosphate (ADP). Glycerol-3-phosphate is oxidised by dihydroxyacetone phosphate (DAP) by glycerolphosphate oxidase (GPO) forming hydrogen peroxide. Peroxidase (POD) catalyzed the H2O2 with 4-aminoantipyrine (4-APP) and 3, 5- dichloro-2-hydroxybenzene sulfonate (DHBS) to produce a quinoneimine dye that shows an maximum absorabences at 520 nm.

The decrease in absorbance at 520 nm is directly proportional to the UA activity in the sample.

MATERIALS PROVIDED

Reagents:

R	Tris buffer, pH 6.8	60 mmol/L
	Glycerolphosphate oxidase (GPO)	≧6000 U/L
	Glycerol kinase (GK)	≧5000 U/L
	Lipoprotein lipase	≧3000 U/L
	Peroxidase (POD)	≧3500 U/L
	Adenosine triphosphate (ATP)	1.0 mmol/L
	4-aminoantipyrine (4-APP)	2.5 mmol/L
	3,5 DHBS	2.0 mmol/L
	Sodium azide	1 g/L

MATERIALS NEEDED BUT NOT PROVIDED

1. Automated chemistry analyzer
2. TG control set (commercially available)

INSTRUMENT

The Kit is applicable on most automated chemistry analyzers. Refer to specific instrument application for suggested settings.

STORAGE AND STABILITY

Store the reagents at 2-8℃. Avoid direct sunlight. The Kit is stable through the expiration date when stored properly. The reagent is stable for 1 month at 2-8℃ after opening.

PRECAUTIONS

1. The Kit is for *in vitro* diagnostic use only. Not for use in humans or animals.
2. The instructions must be followed to obtain accurate results.
3. Do not use the reagents beyond the expiration date.
4. Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.

SPECIMEN COLLECTION AND HANDLING

Follow standard laboratory procedures to collect blood or serum preventing hemolysis.

It is recommended to perform test immediately after sample collection. If the test cannot be done immediately, specimens may be stored at 2~8℃ for 7 days.

TEST PROCEDURE (see Figure 1)

Reagent is liquid stable ready-to-use, no preparation needed.

Calibration: Recommend using included Bioway calibrator set for optimal results.

Test procedure: see Figure 1 and Table 1 for instrument parameter setup. Refer to specific instrument application for suggested setting.

1. Add 3 µl of sample and 300 µl of R1; mix well and incubate at 37℃ for 10 minutes.
2. Take optical density measurement.

3. Calculate average Δ A

RESULT

The amount of TG in mmol/L can be obtained by the following calculation:

$$\text{TG (mmol/L)} = \frac{\Delta A\text{test}}{\Delta A\text{standard}} \times \text{standard solution (mmol/L)}$$

Please refer to instrument application if testing under different conditions.

EXPECTED VALUES

<1.7 mmol/L
It is recommended for each laboratory to establish its own expected values

QUALITY CONTROL

Using commercially available controls with known concentration is recommended before each batch of tests to ensure the test is properly performed and all reagents and the instrument are functional as specified.

LIMITATIONS

1. The Kit is for *in vitro* use on automated chemistry analyzers only.
2. The test result from the Kit should not be used as the only basis for definite diagnosis.
3. Samples with TG exceeding the maximum measurement range should be diluted with saline and retested.

PERFORMANCE CHARACTERISTICS

Linearity: 0 – 11.4 mmol/L (R≥0.990)

Accuracy: Bias proportion 90%~110%

Precision: Within Run: CV≤4%;
Run-to-Run: CV≤5%

Interference: no interference detected for: Unconjugated bilirubin (≦684μmol/L), Ascorbic acid (≦50mg/dl), Bilirubin (≦684μmol /dl), Hemoglobin (≦ 500mg/dl), Heparin, EDTA and Sodium Fluoride in a normal dose.

Reagent Blank Absorbance: At 520nm wavelength and 10mmoptical diameter, O.D. ≤0.10.

REFERENCES

1. Fossati P. *et al*., Clin. Chem., 28:2077-2080 (1982).
2. McGowan MW. *et al*., J. Clin. Path., 29:538 (1983)
3. Trinder P. Ann. Clin. Biochem., 6:24-27 (1969)

Not Intended for Sale in the United States.

Pointe Biotech (Nanjing) Co., Ltd.

No.85,Xingmin South Road, Jiang Ning District, Nanjing,P.R.China 211100
Tel:86-25-52425019,
Fax:86-25-52424836
info@biowaydx.com